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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,353	05/04/2001	James M. Staddon	0623.0410001/EKS/BJD	1015

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/848,353	STADDON ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 C.F.R. 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 21-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1 and 21-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Part III DETAILED ACTION

Status of Claims

Response to restriction requirement filed 08/20/2003 is acknowledged. Applicant's election is noted; however it is deemed moot because the claims addressed in the restriction requirement had been previously canceled pursuant to Preliminary amendment filed 05/04/2001 (which was overlooked by examiner at the time of preparing the restriction requirement). Claims 2-20 are canceled. Claims 21-39 are added. Claims 1,21-39 are pending. Accordingly, the following restriction requirement (which replaces the previous restriction requirement was deemed necessary).

Further restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121¹:

- I. Claim 1, drawn to use of an agent in preparing medicament.
- II. Claims 21-26, drawn to method for increasing permeability of physiological barrier by agent promoting tyrosine phosphorylation.
- III. Claims 27-29, drawn to method for treatment brain oedema.

¹The inventions are only classifiable upon selection of an ultimate compound species.

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- IV. Claims 30,31, drawn to method for treatment peripheral oedema.
- V. Claim 32 , drawn to method for blocking entry of leukocytes into the brain.
- VI. Claim 33, drawn to method for treatment multiple sclerosis.
- VII. Claim 34, drawn to method for prevention of cancer metastasis.
- VIII. Claim 35, drawn to method for increasing transmembrane transport of membrane impermeant compound. using a conjugate
- IX. Claims 36-38, drawn to composition comprising an agent and bioactive compound.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VIII are related as independent and/or patentably distinct methods which are not connected in design, operation or effect. The methods are either not disclosed as capable of use together (e.g., Groups I and II), or have different functions (e.g., Groups VI and VII), or effects (e.g., Groups IV and VII), or different modes of operation.

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The composition of Group X is independent from methods of Groups I-VIII because the methods do not require use of such product as a two-component composition of Group X.

Composition of claim X is patentably distinct from method of Group VIII because the latter uses a conjugate of two components whereas the composition of Group X is a mixture of two products. Further, as an agent broadly defined as being capable of promoting tyrosine kinase phosphorylation is involved in myriads of various physiological processes, the composition of Group X can be used in a plurality of method different from methods of Group IX.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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Species Requirement

Election of species should be required prior to a search on the merits in all applications containing both species claims and generic or Markush claims.(MPEP 808.01(a)).

Upon election of Groups II or VIII the following election of species is hereby required for the initial search for examination on merits:

The claims of Groups are generic to a plurality of disclosed patentably distinct species of agents (Group II) or types of physiological barriers (Group VIII) that require a burdensome classification, and/or bibliographic, manual and computer search. Applicant is required to elect a single disclosed species of each for

I) for Group II, an agent as in claims 24-26 that either a) activates kinase or b)inhibits phosphatase.

II) for Group VIII, a physiological barrier, such as those recited in claims 36-38.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is

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the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

To be complete, a response to the election of species requirement should include a proper election along with a listing of all claims readable thereon, including any claims subsequently added. MPEP 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Mr. Michael Woodward, can be reached at (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

November 12, 2003

